DEC 2 0 2001

K013218

510(k) Summary
[as required by 21 CFR 807.92]

Date Prepared [21 CFR 807.92(a)(1)]

September 19, 2001

Submitter's Information [21 CFR 807.92(a)(1)]

Fujifilm Medical Systems U.S.A., Inc.
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Contact: Joseph M. Azary

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- Fuji Speed Suite
- Fuji Speed Suite Phase II

The device common or classification names are: **Stationary x-ray system**

Predicate Device [21 CFR 807.92(a)(3)]

Fuji identifies the predicate devices as follows:

Siemens Multix TOP/PRO Radiographic Table	K971452
Siemens Multix Compact K bucky table	K001201
Fuji FCR 5501D	K993861
Fuji HI-C654 Multimodality Workstation	K972256
Fuji ID-T741 ID terminal	K993861

Description of the Device [21 CFR 807.92(a)(4)]

Summary of the function of the device and its major components:

The Speed Suite combines the following components and devices in one package.

12) Fuji Computed Radiography Image Reader (FCR 5501D, FCR 5501D-ES, or FCR 5502D table).

13) IIP Workstation
14) ID-T741A ID terminal
15) Siemens X-ray Tube (Optitop 150/40/80HC)
16) Siemens X-ray Generator (Polydoros IT 55)
17) Siemens Automatic Collimator (AL01)
18) Siemens Tube Stand
    a. Floor Mounted Tube Stand Multix-L
    b. Ceiling Mounted Tube Stand 3D Top-ACSS with optional tracking
19) Central electronic unit (ZE)
20) Siemens Multix Compact K bucky table
21) Siemens Rasterwanderat bucky wall stand
22) X-CON software

The Speed Suite utilizes devices that have already received 510(k) marketing clearance from FDA. The primary difference is the addition of the X-CON software that allows the Fuji image readers to communicate and interface with the Siemens X-ray equipment. X-CON refers to a combination of software and hardware that will integrate the Fuji ID-T741 or IIP workstation with the Siemens Polydoros IT 55. The ID-T741 or IIP workstation will interface directly to both the Fuji image reader and to the Polydoros IT55 via cabling. The software for the ID-T741 and IIP workstation is adapted to integrate existing patient anatomical menus according to defaults, so that a selected patient exam will display parameters for an associated x-ray exposure. X-ray exposure menus can be adjusted according to user preferences, and all defaults can be overridden. Once the patient exam is selected, the exposure data information is transferred to the generator, thus initiating the exposure according to directions. After each exposure, the fixed data for kV, mAs and spot size will be sent back to the ID-T741 terminal or IIP workstation.

Intended Use [21 CFR 807.92(a)(5)]

The indications for use for the FUJI SPEED SUITE is the same as the predicate device: radiographic exposures of the entire body specifically the skull, spinal column, chest, and abdomen, as well as extremities, the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject device represents a minor revision to devices that have been already cleared by FDA. The Speed Suite groups Siemens and Fuji devices into one package and includes X-CON software which allows the Fuji Radiographic equipment to communicate with the Siemens X-ray equipment.

Performance Data [21 CFR 807.92(b)(1)]

Based on validation studies and risk analysis, we believe this is a minor change that is of minimal risk.

Conclusion [21 CFR 807.92(b)(3)]

Hospitals usually purchase radiographic image equipment and x-ray equipment separately from different manufacturers. The equipment is usually connected in form or another. Therefore, the Speed Suite does not introduce a new concept or technology.

In conclusion, the subject device is utilizing components that have already been cleared by FDA and have been used safely and effectively in clinical environments. The subject device includes a minor revision to the product involving software that interfaces between Fuji radiographic equipment and Siemens X-ray equipment. At anytime the exposure data can be overridden by the operator/technologist and a manual generator technique can be selected.

The components of the subject device comply with recognized safety and consensus standards.

We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Joseph M. Azary
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Fujifilm Medical Systems USA, Inc.
419 West Ave.
STAMFORD CT 06902

AUG 23 2013

Re: K013218
Trade/Device Name: Fuji Speed Suite™ and Fuji Speed Suite™ Phase II
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: September 19, 2001
Received: September 26, 2001

Dear Mr. Azary:

This letter corrects our substantially equivalent letter of December 20, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5 10(k) Number (if known): K013218

Device Name: Fuji SPEED SUITE

Indications For Use:

The indications for use for the FUJI SPEED SUITE is the same as the predicate device: radiographic exposures of the entire body specifically the skull, spinal column, chest, and abdomen, as well as extremities, the identification, capture, digitization, and processing of diagnostic x-ray images, and associating patient and exam identification with the images.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013218